



Dietary Supplement Labeling Requirements

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Agenda

- The Bottom Line
- The Law and Legal Terms
- Reviewing a “dietary supplement” entry
(What is a dietary supplement?)
- New Dietary Ingredients
- Tainted Products
- Claims
- DS Labels - Class Participation

The Bottom Line

- General Regulatory Paradigm
 - Very, very limited premarket review – **No Premarket approval (New Dietary Ingredients)**
 - No formulation standards
 - No product registration
 - No approval of claims
 - Manufacturer responsible for ensuring safety and compliance
- Where to find Information
 - Statutes (15, 21 & 42 U.S.C)
 - Code of Federal Regulations (Title 21)
 - Guidances

The Bottom Line

- \$34.9 Billion USD in 2013 – Industry (Nutrition Business Journal 2014) +
- Industries within Industry (manufacturers, packagers, labelers, holders, distributors, and warehousers) +
- Approximately 240 spiked products (2012-2014) +
- 150 Million Americans taking Dietary Supplements +
- only 40-50 NDINs annually + 869 NDINs total since DSHEA +
- IOM estimated in 2004--1,000 new DS introduced each year.
Only **4,000** products at the time of DSHEA passage. DSLD—43,460 +
- Regulation accomplished by 20+ FTEs within DDSP = Low Risk? +

*Consumers should have **access** to dietary supplements that **meet quality standards**, that are **free from contamination** and are **accurately labeled**. FDA's review of NDI notifications are an important preventive control mechanism to ensure that the consumer is not exposed to unnecessary public health risks in the form of new ingredients with unknown safety profiles.*

The Law - Statutory Authority

- Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. § 301 et. seq.)
 - **Dietary Supplement Health and Education Act of 1994 (Pub. L. 103-417, 108 Stat. 4325)**
 - Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109-462, 120 Stat. 3469) ... 760, 761 (AER Bill)
 - Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171, 116 Stat. 135-527)
 - Food Allergen Labeling and Consumer Protection Act of 2004 (Pub. L. 108-282, 118 Stat. 905)
 - Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188, 116 Stat. 594)
 - **FDA Food Safety Modernization Act (Pub. L. 111-353, 124 Stat. 3885)**
 - Fair Packaging and Labeling Act
 - Public Health Service Act

Major Dietary Supplement Provisions of the Act

- “Dietary supplements” are deemed (as food)
- Defined “dietary supplement” [21 U.S.C. 321(ff)(1) section 201(ff)(1)]
- Established requirement for “new dietary ingredients” [21 U.S.C. 350b section 413]
- The elements of how a food is determined to be safe are appropriate for DS
- There is an Adulteration (safety) standard specific to supplement products and their ingredients
- DSHEA specifically exempted FAP/GRAS provisions for DS – but added new adulteration provisions [21 U.S.C. 342 section 402]
- The Act has requirements for **labeling** and **claims**
- Current Good Manufacturing (**cGMPs**) are provided for dietary supplements
- Adverse events reports (**AERs**) must be kept and serious AERs reported to FDA within 15 days

What Can FDA Use?

- cGMPs
- SAERs
- **Labeling**, Facility Registration, etc.
- **New Dietary Ingredient Notifications** (NDINs)
- * NDIs are the only premarket preventive control with respect to the regulation of dietary supplements

Reviewing a “dietary supplement” entry

- **Is it a dietary supplement?**
- **Does it contain legitimate dietary ingredients?**
- **Are there any “new dietary ingredients” for which a notification is required?**
- **Does it have acceptable identity and “supplement facts” labeling?**
- **Are there disease or structure/function claims in labeling?**

NNFA - National Nutritional Foods Association, NNFA List of Dietary Supplement Ingredients In Use Before October 15, 1994 (April 26, 1996). Docket No. FDA-2005-P-0259 [Document ID: FDA-2005-P-0259-0012].

Council for Responsible Nutrition, CRN List of Dietary Ingredients “Grandfathered” Under DSHEA (September 1998). Docket No. FDA-2005-P-0259 [Document ID: FDA-2005-P-0259-0010].

What is a dietary supplement?

- Defined in section 201(ff) of the Act (21 U.S.C. § 321(ff)(1))
- “...a product (other than tobacco) intended to supplement the diet that bears or contains one or more...” dietary ingredients

“Intended to supplement the diet”

- **Supplement**: “augment diet to promote health and reduce risk of disease”
- **Diet**: “usual food or drink of man”
- Intent is evidenced by representations made for the product
- **Example**: Not include street drug alternatives* (sec 505, 502 Act), oral analgesics

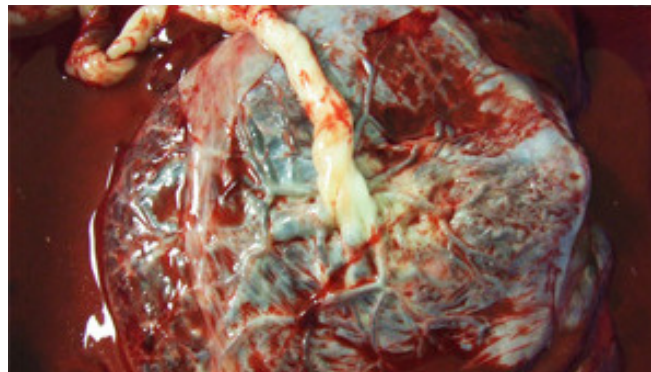
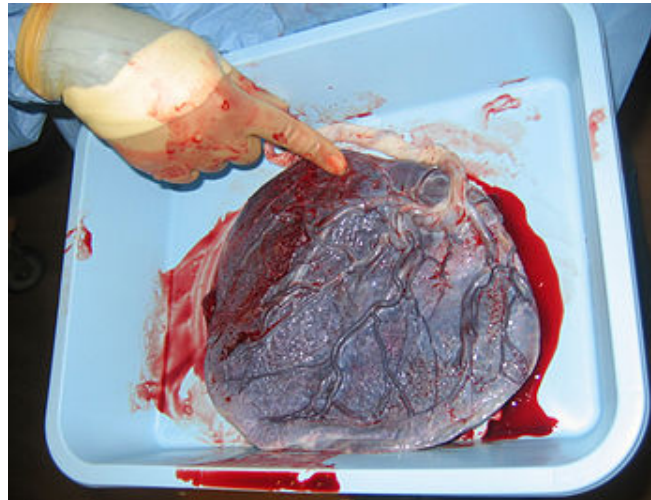


* 62 Fed. Reg. 30678, 30699-700 (June 4, 1997)

What are dietary ingredients?

- **Vitamin, mineral, amino acid**
 - **Not limited to “nutritionally essential”**
- **Herb or other botanical**
 - **The whole or any physical part of a plant**
- **Dietary substance for use by man to supplement the diet by increasing the total dietary intake**
- **Extract, constituent, combination, concentrate, metabolite of any of above**

“Dietary substance for use by man”



“Dietary substance for use by man”

- Of or pertaining to the usual food or drink of man**
 - Does not mean “any” substance**
 - Not limited to US diet**
 - Limited to human use**
- does not include Human tissue, pathogenic bacteria**

What is a dietary supplement?

- **Intended for ingestion**
 - **US v. Ten Cartons Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F. 3d 285 (2d Cir. 1995)**
- **Pill, powder, capsule, liquid**
- **Not represented for use as conventional food or meal replacement (not sole item of a meal or diet)**
- **NOT INCLUDE certain approved drugs or investigational drugs**

“Intended for Ingestion”

- Ordinary and plain meaning of “ingestion”
- Take into stomach and gastrointestinal tract enterally
- Not include:
 - External/topical products, patches
 - Mouthwashes, rinses
 - Nasal/inhaled products
 - Some sub-linguals and lozenges

21 U.S.C. § 321(ff)(2)

US v. Ten Cartons Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff’d, 72 F. 3d 285 (2d Cir. 1995)

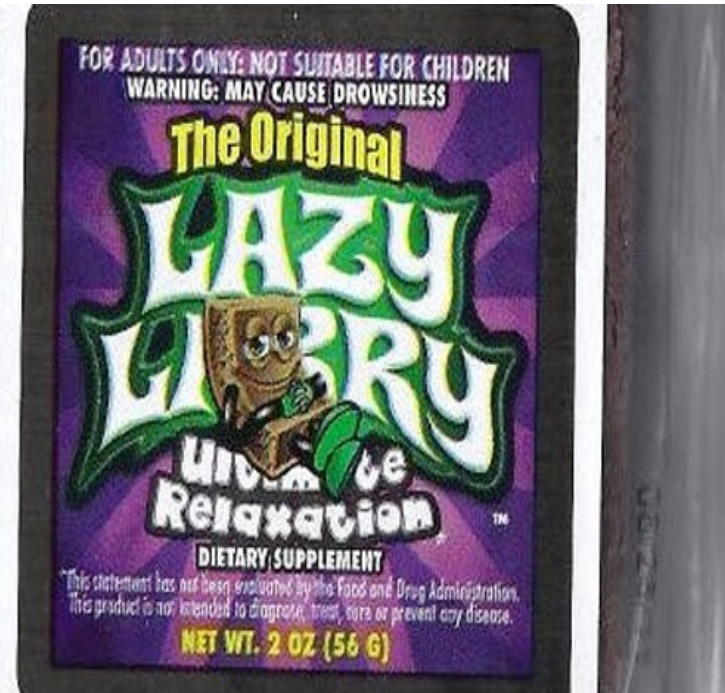
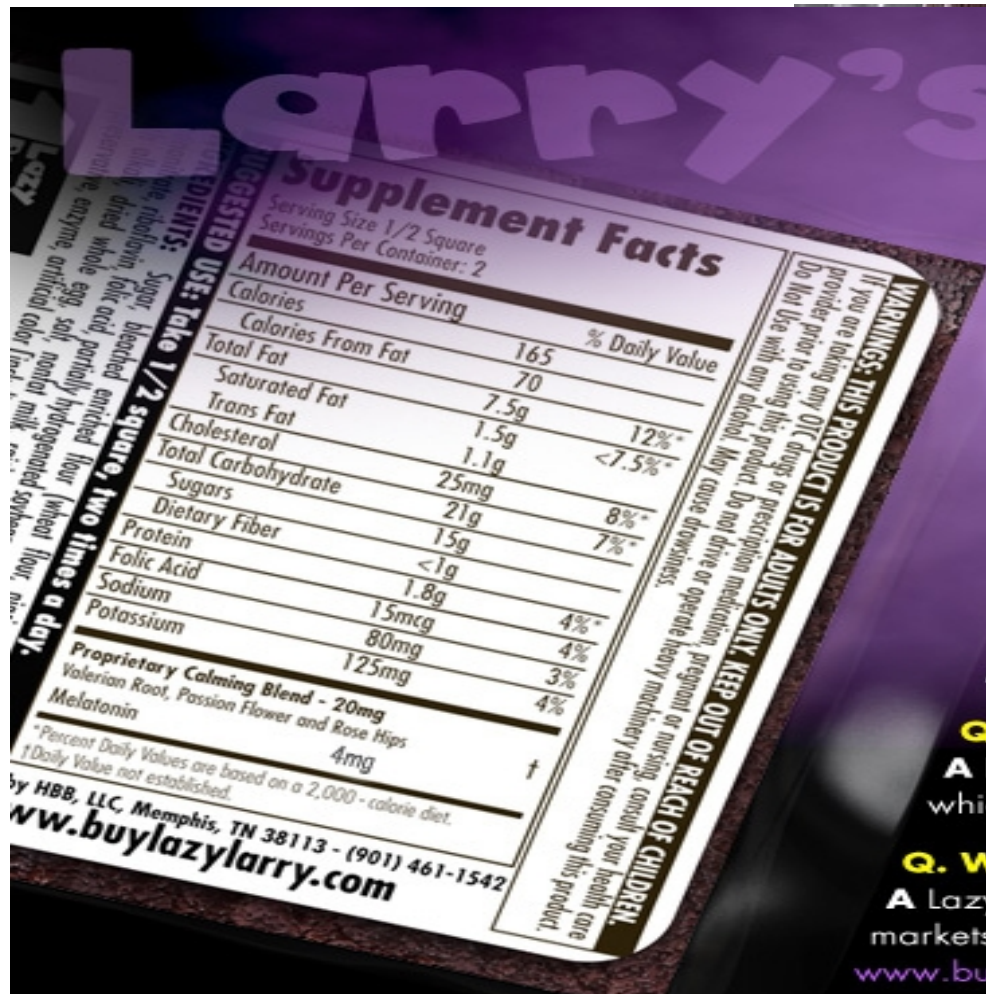
“Represented for use as conventional food”

- **Not same as prior “simulate conventional food” definition (i.e., “conventional food form”)**
- **Physical attributes not generally determinative**
 - **No reliance on a single criteria, case by case**
- **Think “how is it used” or “what is it a substitute for”**
 - **Uses common or usual food name, such as snack, brownie, cookie, or beverage**
 - **Uses standardized food name**
 - **Uses label representations/pictures that suggest conventional food uses**
 - **packaged like a conventional food**
 - **used or represented as alternative to a food**

“Represented for use as conventional food”



“Represented for use as conventional food”



What is Not a dietary ingredient?

- **Synthetic copy of a component of a plant**
- **Most newly synthesized chemicals**
- **Pathogens, contaminants and most bacteria**
- **Metabolite (without evidence)**
- **Most approved new drugs and many investigational new drugs**

[21 U.S.C. § 321(ff)(3)]

Approved/Investigational Drugs

- **Does not include an article that is an**
 - **Approved drug, antibiotic, biologic**
 - **Authorized investigational drug, etc.**

UNLESS

- **Marketed as food/dietary supplement before such authorization or approval**
 - **21 U.S.C. § 321(ff)(3)**

New Dietary Ingredients

- Defined in section 413 of the Act**
- How they fit under the Act is defined in 201(ff)**
- Not marketed in the US before October 15, 1994 [413 (d) DEFINITION]**
- Some require notifications before they can be lawfully marketed**
- No authoritative list of grandfathered dietary ingredients**

NDIs: What to Submit?

- **Who submits? Manufacturer or distributor.**
- **Must be filed at least 75 days before the product is introduced into interstate commerce**
- **Confidential for 90 days, then placed on the public docket (trade secrets, etc are redacted)**
- **Table of contents or fillable form (no electronic submission yet)**

NDIs and NDI Guidance to Industry

- ❖ **Notifications are not optional: A dietary supplement marketed without a notification is adulterated.**
- ❖ **The NDI provision represents a major safety “gate”: there must be adequate evidence about the safety of supplements containing new dietary ingredients.**
- ❖ **FDA receives 40-50 notifications per year**
- ❖ **In actuality, only 600 NDIs out of 869 to date in our database are unique.**

NDIs: Safety Responsibilities

- The manufacturer or distributor of a supplement product is responsible for ensuring that it is safe before it is marketed in the U.S.
 - End of 413 (a)(2) -*“that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe”*
- FDA is responsible for taking action against any unsafe products after they are marketed in the U.S.

A dietary supplement containing an NDI is adulterated unless:

- ❖ **The dietary supplement contains only dietary ingredients that have been present in the food supply as an “article used for food” in a form in which the food has not been chemically altered**
- or
- ❖ **The manufacturer or distributor submits a pre-market notification to FDA that contains history of use or other evidence of safety establishing that the supplement “will reasonably be expected to be safe” when used as recommended/suggested in the product’s labeling**

The Act § 413(a)

New Dietary Ingredients

- Adulterated by operation of law unless one of two conditions met:**
 - Present in food supply as article used for food and not chemically altered**
 - Has history of use or other evidence of safety AND party notifies FDA 75 days prior to marketing.**

New Dietary Ingredients

- How do you know?**
 - You do not!!**
 - Address on case-by-case basis (watch for new import alerts)**
 - Emerging policy**
 - Contact Cara Welch or Ali Abdel-Rahman**
 - Prior detentions**
 - Circumstances change rapidly**
 - Chemical entities most eligible**
 - Botanical/botanical extract unlikely**

“Tainted” Product Categories

- **Weight Loss:**
 - Japan Weight Loss, FrutaPlanta, 2 Day Diet
- **Sexual Enhancement:**
 - Ten Hard Days, Man King, RegenArouse (for females)
- **Body Building:**
 - Superdrol, 6-OXO, Trenadrol, X-Tren
- **Diabetes, BPH, Pain and arthritis, Sleep aids**

Hidden Ingredients

- **Prescription drug ingredients, including controlled substances**
- **Analogues of prescription drug ingredients**
- **Unapproved scheduled controlled substances**
- **Ingredients with an IND and under clinical investigation**
- **Novel ingredients that have never been studied in humans**
- **Ingredients approved as drugs in other countries**
- **Ingredients that have been removed from the US market for safety reasons**



Sexual Enhancement Products (2012-2014)

Hidden Ingredients

***sildenafil** – erectile dysfunction drug (Viagra)

***propoxyphenylsildenafil** – analogue of sildenafil

***hydroxythiohomosildenafil** – analogue of sildenafil

***sulfoildenafil** — analogue of sildenafil

dimethylsildenafil – analogue of sildenafil

dimethylacetildenafil – analogue of sildenafil

desmethylcarbondenafil – analogue of sildenafil

noracetildenafil – analogue of sildenafil

***tadalafil** – erectile dysfunction drug (Cialis)

aminotadalafil – analogue of sildenafil

***thioaidenafil** – analogue of sildenafil

vardenafil – erectile dysfunction drug (Levitra)

dapoxetine – not approved in U.S. (studied as antidepressant and approved in some countries for premature ejaculation)

*one of the six drugs identified in 2014



Examples:

STUD Capsules
 Extenze Tablets
 X-Rock
 Firminte
 Libigrow
 Casanoa
 Night Bullet
 AFFIRM XL
 Super Cheetah

Weight Loss Products (2012-2014) Hidden Ingredients

***1,3-dimethylamylamine (DMAA)** -- not a dietary ingredient

***sibutramine** – controlled substance and obesity drug
(withdrawn due to safety concerns)

n-desmethysibutramine – analogue of sibutramine

n-di-desmethysibutramine – analogue of sibutramine

***phenolphthalein** – cancer-causing risk

ephedrine alkaloids – cardiovascular stimulant

***fluoxetine** – antidepressant

triamterene – diuretic

***lorcaserin**—obesity drug

*one of five drugs identified in 2014



Examples:

Ultimate Formula Bee Pollen
Fat Zero
Bethel 30
Beautiful Slim Body
Super Slim
1 Day Diet
Slim Max
Be Inspired

Labeling - Overview

- **General and nutrition labeling (21 CFR Part 101)**
 - **21 CFR § 101.3(g)** – Identity labeled as DS
 - **Supplement Facts (mixing of (b)(2) and (b)(3) ingredients**
 - **101.9 (correct nomenclature), § 101.36 (ordering)**
 - **21 CFR § 101.15(c) product labels contain information in two languages but does not appear to repeat**
 - **AER label statement (domestic address/phone) ... 403(y)**

Labeling – Overview Continued

- **General and nutrition labeling (21 CFR Part 101)**
 - **Ingredient list 21 CFR § 101.4(a)(1)**
 - **Name and place of business of manufacturer, packer, or distributor 21 CFR § 101.5**
 - **Net quantity of contents § 101.105(a)**

Requirements Unique to Supplements

- **Iron warning statement - § 101.17(e)**
- **Claim disclaimer statement - § 101.93(b-f)**
- **“Dietary Supplement” statement of identity - § 101.3(g)**
- **§ 101.4(h) – common or usual name, part of plant from which DI is derived**
- **403(y) – Domestic Address or phone # for sAER**
- **“Structure/function” claims pursuant to § 403(r)(6)**

Identity Labeling-- § 101.3

§ 101.3 (g) - Must use term “Dietary supplement” or authorized descriptive alternative that reflects ingredients (e.g., “energy supplement” for liquid dietary supplements intended to supplement the diet with ingredients that provide “energy”)

§ 101.3(d) - Location of identity statement

- Principal display panel**
- Bold type**
- Parallel to the base of package as designed to be displayed**

§ 101.36 - Nutrition Labeling of Dietary Supplements

Consistent with § 101.9 except:

- Titled “Supplement Facts”**
- Can declare all dietary ingredients**
- May include source in facts panel**
- Special requirements for plant ingredients**

“Supplement Facts”

Two sections in panel

**(b)(2) - Dietary ingredients having
Recommended Daily Intakes (RDIs) or
Daily Recommended Values (DRVs) (i.e.,
nutrients)**

(b)(3) - “Other” dietary ingredients

“(b)(3)” Other Dietary Ingredients (RDI’s and DRV’s--not established)

- List by common or usual name — any order**
- List quantitative amount by weight**
- Have footnote “Daily Value not established”**
- Must state part of plant (English)**
- Common or usual name in *Herbs of Commerce***
- Latin name if not in *Herbs of Commerce***

“(b)(2)” Nutrients Must List **(§ 101.36(b)(2))—RDI’s/DRV’s established)**

Calories

Calories from fat

Total fat

Saturated fat

Cholesterol

Sodium

Total carbohydrate

Dietary fiber

Sugars

Protein

Vitamin A

Vitamin C

Calcium

Iron

Voluntary (b)(2) Nutrients

Only required if a claim is made or is added:

- calories from saturated fat**
- sugar alcohol**
- monounsaturated fat**
- soluble fiber**

Insoluble fiber

Polyunsaturated fat

Other carbohydrate

Others w/ RDI/DV

Information on Nutrients

- Only if greater than “zero” amount**
- Name**
- Amount (column or next to)**
- % Daily Values/RDI**
- Use adult values, but alternatives allowed based on intended use**

Source Information § 101.36(d)

- May be listed in the nutrition label
“Calcium” (as calcium carbonate)**
- Or listed in the ingredient statement**
- Not required to list twice**

Proprietary Blends - § 101.36 (c)

- Use term “Proprietary Blend” or other descriptive/fanciful name**
- List Ingredients under heading in descending order**
- Linear or column format**
- Special requirements for extracts—
§ 101.36(b)(3)(ii)(B)**



Supplement Facts

Serving Size 1 tsp (3 g) (makes 8 fl oz prepared)

Servings Per Container 24

	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	< 1%*
Sugars	2 g	†
Proprietary blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaves)		†

* Percent Daily Values are based on a 2,000 calorie diet.

† Daily Value not established.



Supplement Facts

Serving Size 1 Tablet

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	5000 IU	100%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D (as cholecalciferol)	400 IU	100%
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU	100%
Thiamin (as thiamin mononitrate)	1.5 mg	100%
Riboflavin	1.7 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C yellow No. 6, propylene glycol, propylparaben, and sodium benzoate.

Exceptions In Regulation--§ 101.36(i)

- Type size and format for small packages**
- No need for nutrition labeling**
 - Bulk form not for distribution to consumers**
 - Small business**

Types of Dietary Supplement Claims

- **Prohibited Disease Claims**
- **Permissible Health Claims**
- **Permissible Structure/Function” Claims**
pursuant to § 403(r)(6)
(unique to Dietary Supplements)
- **Nutrient Content Claims**

Disclaimer Statement

(only required if structure/function claim exists)

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

“Structure/Function Final Rule”

- **January 6, 2000 Federal Register (65 FR 1000)**
 - **defined the term “disease”**
 - **identified 10 criteria to assist defining the term**
 - **Substantiation of the claim**

“Structure-Function” Claims

- **Section 403(r)(6) & 21 CFR 101.93**
 - **classical nutrient deficiency disease
AND discloses prevalence of disease**
 - **affect on structure or function**
 - **mechanism of affect on
structure/function**
 - **describes general well-being**

“Structure-Function” Claims

- **May not claim to diagnose, treat, cure, or prevent any disease**
- **Disease defined in 21 CFR 101.93(g)**
- **See January 6, 2000 Federal Register (65 FR 1000)**

Substantiation

§(403)(r)(6)(B)

- **Claim must be truthful and not misleading**
- **Must be supported by competent and reliable scientific evidence**

Intent of the Rule

- **Define universe of claims that are explicit and implicit disease claims**
- **Not:**
 - **Apply to other FDA regulated products**
 - **Interpret other provisions of the Act**
 - **Define “appropriate” s/f claims**
 - **Address substantiation**

Disease Claims Define the Product

Disease:

“damage to an organ, part, structure, or system of the body such that it does not function properly...or a state of health leading to such dysfunctioning...”

2 Elements of the Definition

- **“Damage...not function properly”**
 - **Damage = Direct evidence of damage; i.e., pathology**
 - **Not function properly = consequence of abnormal condition/damage**

2 Elements of the Definition

- **“State of health leading to such dysfunctioning”**
 - **Health related condition**
 - **Migraine, hypertension, psychiatric diseases**

Definition is Broad

- **Not limited to serious diseases**
- **Includes signs/symptoms that do not require a drug or doctor**
 - **Act doesn't distinguish minor vs serious**
 - **Congress was silent on this matter**

Caveats of Disease Claims

- Context is CRITICAL
 - Not always possible to draw a clear line
 - Need to consider all information in labeling and elsewhere
 - No claim is likely to be always or never appropriate

Caveats of Disease Claims

- **Claimed effects need not be “nutritional”**
- **Drug claims DO NOT equal disease claims**
 - **some drugs approved for s/f effects**

Class Participation - Claims

treat

cure

prevent

diagnose

mitigate

stimulate

maintain

support

regulate

promote

- **Are verbs disease claims??**

Words as Implied Claims

- **“Maintain normal or healthy”**
 - **How characteristic is it?**
 - **Linked to particular population?**
 - **Linked to deviations from normal?**
 - **Marker or symptom quantifiably linked to disease?**
 - **supports secretory IgA**
 - **supports NK cells**
 - **Context must limit scope of the claim**



Class Participation

Labels



Materna®

PRENATAL • POSTPARTUM VITAMIN AND MINERAL SUPPLEMENT

The American Dietetic and Hydrocephalus Association of Canada recognizes Materna as a good supplemental source of Folic Acid.

EACH TABLET CONTAINS:

VITAMINS

Beta-Carotene (a source of vitamin A).....	1500 mcg / 2500 IU
Vitamin A (vitamin A acetate)	300 mcg / 1000 IU
Vitamin E (dl-α tocopheryl acetate)	13.5 mg / 30 IU
Vitamin C (ascorbic acid).....	85 mg
Folic Acid (folate).....	1 mg
Vitamin B1 (thiamine mononitrate)....	1.4 mg
Vitamin B2 (riboflavin).....	1.4 mg
Niacinamide.....	18 mg
Vitamin B6 (pyridoxine hydrochloride).....	1.9 mg
Vitamin B12 (cyanocobalamin).....	2.6 mcg
Vitamin D (cholecalciferol)....	10 mcg / 400 IU
Biotin.....	30 mcg
Pantothenic Acid (calcium d-pantothenate).....	6 mg

MINERALS

Calcium (calcium carbonate).....	250 mg
Magnesium (magnesium oxide).....	50 mg
Iodine (potassium iodide).....	220 mcg
Iron (ferrous fumarate).....	27 mg
Copper (cupric sulphate).....	1 mg
Chromium (chromium chloride).....	30 mcg
Manganese (manganese sulphate).....	2 mg
Molybdenum (sodium molybdate).....	50 mcg
Selenium (sodium selenate).....	30 mcg
Zinc (zinc oxide).....	7.5 mg

CAUTION: Do not exceed the recommended daily dose. If taking other supplements, read label, as other supplements may contain the same ingredients. In case of accidental overdose, contact a physician or poison control centre immediately.

● There is enough iron in this package to seriously harm a child. **Keep out of reach of children.**

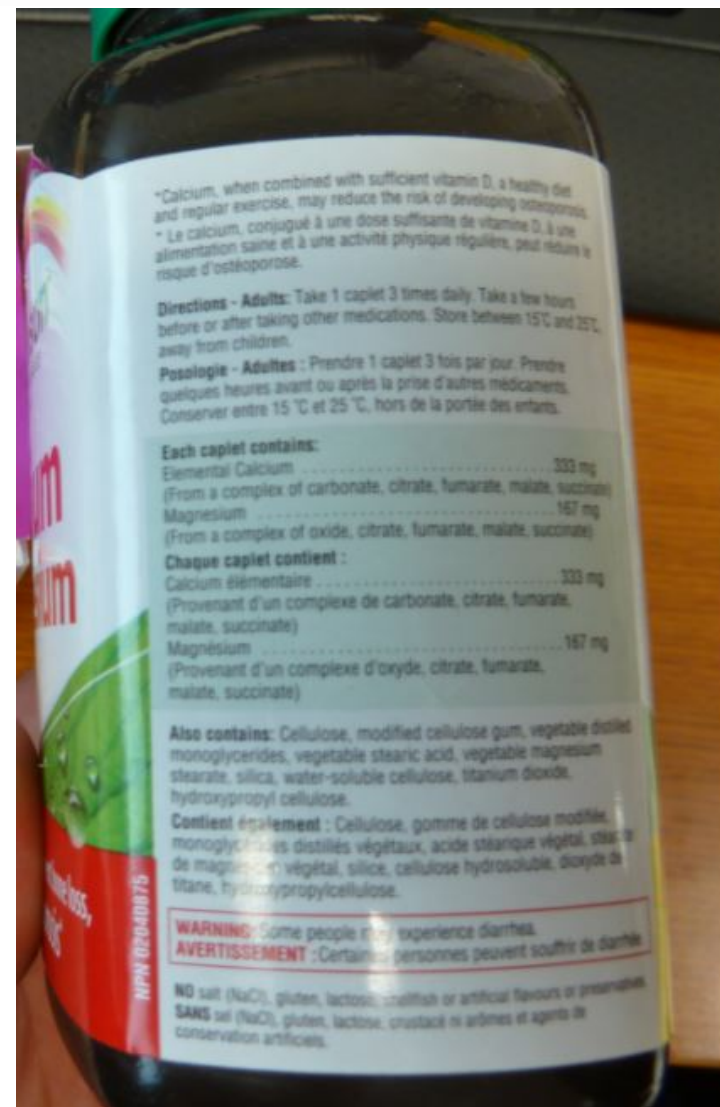
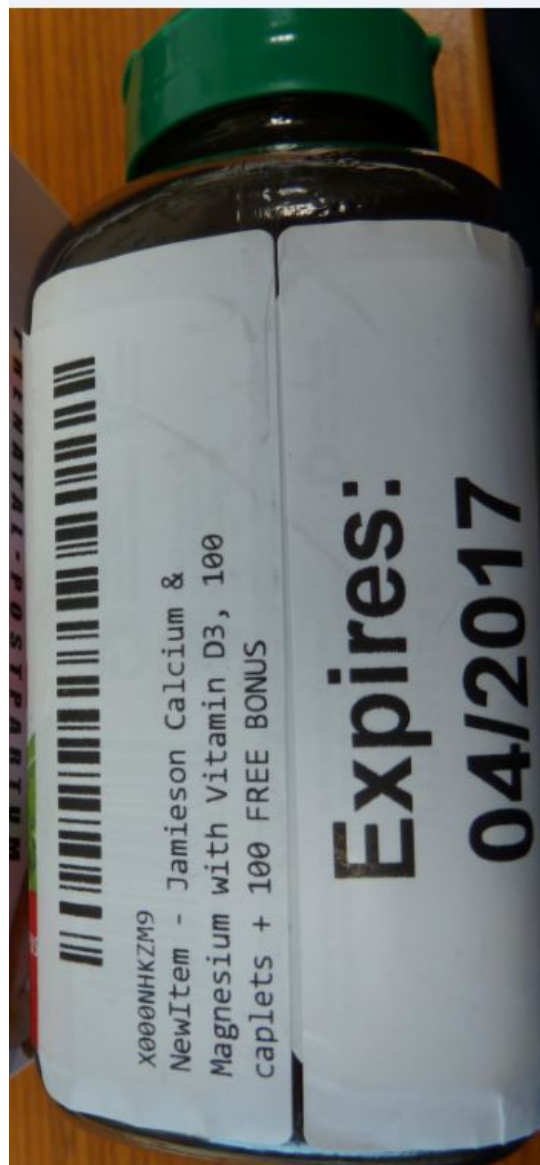
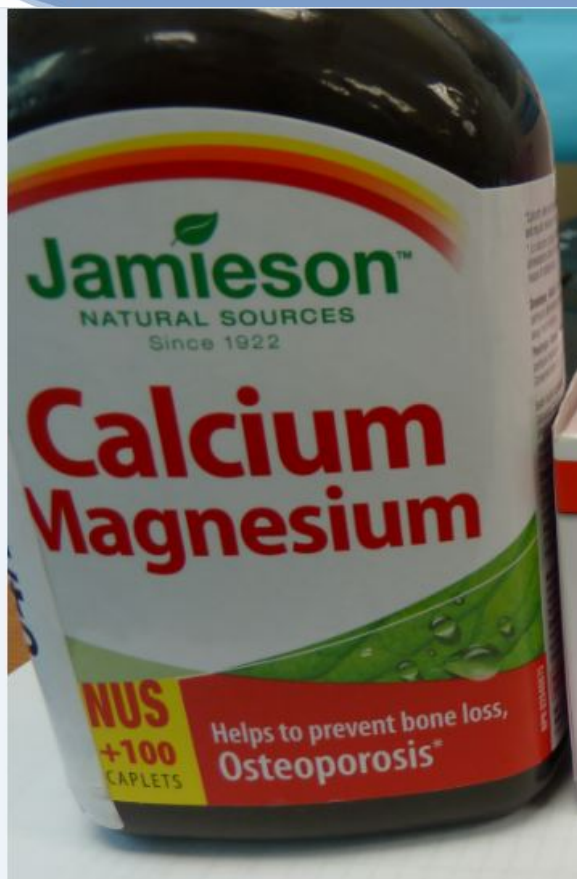
Non-medicinal ingredients: Ascorbyl palmitate, BHT, calcium phosphate, celluloses, citric acid, corn starch, croscovidone, FD&C red no. 40, gelatin, lactose, magnesium stearate, mineral oil, modified food starch, polysorbate 80, silicon dioxide, sodium aluminosilicate, sodium ascorbate, sodium benzoate, sodium citrate, sodium lauryl sulphate, sorbic acid, soybean oil, stearic acid, sucrose, titanium dioxide, triethyl citrate.

No added gluten, parabens, peanut oil or tartrazine (FD&C Yellow No. 5).

ADULT DOSAGE (19 years and over)
1 tablet daily with food prior to conception, pregnancy and when breastfeeding.
Take a few hours before or after taking other medications.

Store at room temperature (15-30°C)
Protect from moisture
Bottle mouth sealed for package use
Child resistant cap

* When taken daily prior to becoming pregnant and during early pregnancy



180 ml

TONICO

HIERRO VIT

B-12

RECONSTITUYENTE
"ANTIANEMICO"

C.N. MED 101100 MMXI-XI

Made
42 AÑOS
de la Universidad de la Salud

HIERROVIT® es un reconstituyente rico en "HIERRO ABSORBIBLE" y vitaminas que son necesarias para la formación de glóbulos rojos de la sangre. HIERROVIT® está indicado para forma cuerpos resistentes a las enfermedades. HIERROVIT® presenta estados anémicos, falta de apetito, hombres, mujeres y niños que presentan por deficiencia alimenticia, convalecencia y desnutrición, cefaleas y mareos por deficiencia del cuerpo en general.

* Ver Lote y Fecha de Vencimiento en la etiqueta del frasco.

Monténgase fuera del alcance de los niños. Guárdese al abrigo de la luz en un lugar fresco y seco, a una temperatura no mayor a 30 °C.

HIERRO-VIT®

180 ml

TONICO

HIERRO VIT

IRON VIT Supplement Facts

Serving Size 2.5 Fl Oz (100 ml)	Each 10 c.c. Contains:
Amount per serving	%Daily Value
Folic acid	04 mg
Iron (as ferrous gluconate)	10 mg
Vitamin B12 (Cyanocobalamin)	1 mcg
Vitamin B1 (Thiamine HCL)	5 mg
Vitamin B6 (Pyridoxine HCL)	1 mg
Vitamin B2 (Riboflavin)	4 mg
Calcium Glycero-phosphate	50 mg
Zinc (as zinc sulfate)	2mg

Other ingredients: Iron, Oxide ferri, Vitamin B12, B1, B6 and B2, Calcium, Zinc, Hematinic supplying Iron, Zinc and vitamin B complex

WARNINGS: KEEP OUT OF REACH OF CHILDREN.

IRON VIT, TONIC

- * Restorative elixir, vitality
- Vitamin & iron supplement, and body general.
- Appetite stimulant.
- * Contains iron and vitamin B12, vitamin A, Panthenol iron deficiency

Precautions: Do not exceed the maximum dose discontinues if any adverse reaction to this product as it is; gastrointestinal intolerance. Hypersensitivity to any components of model.

- * No I use in diabetic and alcoholic patient.
- * It is indicated for deficiency of iron, minerals and vitamin.

Router of administration: Oral sale without medical prescription, store, in cool and dry place

Adult dose: one tablespoon before each meal. the formula has been carefully, balance with vitamins and minerals increased requirement in our body to give you a tonic to help you perform, indeed their daily work.

Distributor: Campeero Latin Distribution
16 Forest Parkway, stall 26 # 29-32
Forest Park, GA 30297
Tel. 770-310-6275 770-846-6819

DOSIS

Adultos: 3 cucharadas al día antes o después de las comidas.
Niños: 1 o 2 cucharaditas 3 veces al día.

Hecho en Honduras por:

LABORATORIOS QUIMIFAR S.A. DE C.V.

Km 1 Carretera a Puerto Cortés, San Pedro Sula, Honduras C.A.
www.quimifar.hn - e-mail: ventas@quimifar.hn - Línea Gratuita: 800 2545-3730

REGISTROS SANITARIOS
Honduras: M-02223

El Salvador: RH-0614210404

Guatemala: 1276
Nicaragua: RF-1064-0804 - Rec. Mhuo
Rep. Dominicana:

FÓRMULA

Cada 100 ml contienen:

Citrato Férrico Amoniacal	985 mg
Oxido Férrico Azucarado	935 mg
Vitamina B12	200 mcg
Vitamina B6	10 mg
Pantenol /Vitamina B5	20 mg
Alcohol	12 %
Agua destilada aromatizado c.b.p.	100 ml

ENERGIL

i...energía todo el día!

ENERGIL

Con Hierro/ With Iron

...Energía todo el día!...Energy all day long!

Supplement Facts

Serving Size: 1 tablespoonful (15 ml)	
Servings per container: 15	
Amount per serving	% Daily Value
Vitamin A (as Palmitate)	1300 IU 26%
Vitamin C (as Ascorbic Acid)	60 mg 100%
Vitamin D3 (as Cholecalciferol)	400 IU 100%
Vitamin E (DL- α -Tocopheryl Acetate)	30 IU 100%
Inositol (as Inositol Hydrochloride)	1.5 mg 100%
Riboflavin (as Riboflavin-5 Phosphate)	1.7 mg 100%
Niacin (as Niacinamide)	20 mg 100%
Vitamin B6 (as Pyridoxine Hydrochloride)	2 mg 100%
Vitamin B12 (as Cyanocobalamin)	6 mcg 100%
Biotin	300 mcg 100%
Phanthothenic Acid (as Depanthothenol)	10 mg 100%
Iron (as Ferrous Gluconate)	9 mg 50%
Iodine (as Potassium Iodide)	150 mcg 100%
Zinc (as Zinc Gluconate)	3 mg 20%
Manganese (as Manganese Chloride)	2 mg 100%
Chromium (as Chromium Chloride)	25 mcg 21%
Molybdenum (as Sodium Molybdate)	25 mcg 33%

Other ingredients: Glycerin, purified water, sucrose, polysorbate 60, citric acid, lemon flavor, sodium benzoate, orange flavor, butylated hydroxyanisole, edetic acid, sodium citrate may be added to adjust pH.

- ★ Restorative elixer, that gives energy vitamin & iron supplement and body general appetite stimulant.
- ★ Contains iron and vitamin B12, vitamin A, vitamin D nourishment reinforcement.

★ Precautions: Do not exceed the maximum dose discontinue if any adverse reaction to this product as it is: Gastrointestinal intolerance. Hypersensitivity to any components of model.

★ No use in diabetic and alcoholic patient.

★ It is indicated for deficiency of iron, minerals and vitamin.

Router of administration: oral safe without medical prescription store, in cool and dry place.

Adult dose: one tablespoon 4 times day each meal.

Energil: Its formula High quality ingredients create the perfect balance, which guarantee fast and effective resultados. Ideal for men, women perform, indeed their daily work.

Distribuidor: Campeero Latin Distribution
16 Forest Parkway, stall 28 # 29-32
Forest Park, GA 30297
Tel. 770-310-6275 770-848-6819

Fórmula:

Vitamina A 5 000 U.I.
Vitamina D 1 000 U.I.
Tiamina HCL 124.5 mg
Riboflavina 4.00 mg
Niacinamida 36.6 mg
Piridoxina HCL 4.99 mg
Vitamina B-12
(Cianocobalamina) 13.00 µg
D-Pantenol 10 mg
Citrato de Hierro Amonio
(Equivalente a 87 mg de hierro elemental),
Alcohol 12% sabor, preservantes y agua c.s.p. 100 ml

Registro Sanitario:

Honduras: M-02602

Instrucciones:

Venta sin receta médica.

Condiciones de almacenaje:

Guardar a temperatura ambiente, evitar la humedad y el calor excesivo.

Vía de administración: Oral

Mantener fuera del alcance de los niños.



Lote:

130946
07/2015

Vencimiento:



ISO
9001:2008
Sistema de
Gestión de Calidad

Producto Centroamericano
fabricado en Honduras por:
INFARMA. Colonia El Prado
Tel. (504) 2225-1272
www.infarma.hn

ENERGIL

i...energía todo el día!



RECONSTITUYENTE QUE DA

Energía, fuerza y vitalidad
con vitaminas B-12 y hierro

- Para aumentar la energía física y mental.
- Prevenir las anemias comunes.
- Controlar la debilidad general y el decaimiento.
- Estimular el apetito.
- Como complemento vitamínico y de hierro.
- Refuerza la alimentación.

Dosis:

Adultos: Tomar 4 cucharadas al día

Niños de 4 a 8 años: Tomar una cucharadita 4 veces al día.

Niños de 8 a 12 años: Tomar dos cucharaditas 4 veces al día.

Tómese antes de las comidas y al acostarse.

Contraindicaciones:

Hipersensibilidad al fármaco.

Advertencias:

Si está embarazada o en período de lactancia consultar al médico antes de usar este producto.

Precaución en personas alcohólicas.

RECONSTITUYENTE QUE DA
Energía, fuerza y vitalidad
con vitaminas B-12 y hierro

Producto Centroamericano
fabricado en Honduras por:
INFARMA. Colonia El Prado
Tel. (504) 2225-1272
www.infarma.hn

250 ml

Infarma

250 ml

Infarma

Vitaminas y
enriquecido
cápsulas
Pharma
Men

Men



Complete
plus for men
state health,
alth, healthy
nes strength,
thy skin and
nt energizer.
0 capsules

Investigaciones científicas señalan que el cáncer de próstata es diagnosticado con mayor frecuencia en hombres a partir de los 40 años, por lo anterior sugieren que el consumo de lycopene y saw palmeto ayudan a reducir el riesgo de desarrollar cáncer de próstata.

Pharma+Men es un multivitamínico completo con los nutrientes necesarios incluyendo el Lycopene y Saw Palmeto para una próstata saludable

*Dr.
Octavius*

Modo de Uso:
Tomar una cápsula diaria
con el desayuno, no exceder
de 2 cápsulas al día.

No se deje al alcance de los niños.
Consérvese en lugar fresco y seco.



LABORATORIOS NORDIMEX CO.
San Francisco, CA. 94538
Dist By:

NUEVA FORMULA

Pharma+Men

cápsulas

Vitaminas y Minerales
enriquecido con
GINSENG PANAX
CoQ10
LYCOPENE



Multivitamínico plus
formulado especialmente
para hombres ayudando
a prevenir problemas de:
Próstata, Corazón, Presión Alta
Huesos, Problemas de la piel
Es un excelente energizante
Frasco con 30 cápsulas

Pharma+Men
cápsulas

Supplement Facts

Serving Size	1 Capsule	
Servings Per Container	30	
		% DV
Vitamin A	2667 IU	55%
Vitamin B1	1.4 mg	100%
Vitamin B2	1.6 mg	100%
Vitamin B6	2 mg	100%
Vitamin B12 1%	0.1 mg	100%
Vitamin E	14.9 IU	50%
Vitamin D3	200 UI	50%
Vitamin B3	18 mg	100%
Vitamin C	60 mg	100%
Vitamin K	5 mcg	25%
Selenium	50 mcg	**
Ginseng panax 6/24	40 mg	**
Manganese sulfate	7.75 mg	**
Biotin	0.15 mg	**
Folic Acid	0.1 mg	**
Copper Citrate	5.6 mg	**
Sodium Selenite	0.111 mg	**
Magnesium Oxide	73 mg	18%
Zinc Citrate	2.75 mg	25%
Calcium Carbonate	250 mg	**
Lecithin	100 mg	**
Lycopene	5 mg	**
CoQ10	5 mg	**
Saw Palmetto 30% Ext.	25mg	**

**Daily value not established. % DV Based on a 2,000 Calorie Diet.

Other Ingredients: Gelatin, magnesium stearate, water. Contains corn and rice. This product contains NO milk, egg, fish, peanuts, crustacean shellfish, tree nuts, wheat, yeast, or gluten. Contains NO artificial sweeteners, flavors, colors or preservatives.

Dosage and Use: Take one capsule with breakfast, or as recommended by a healthcare practitioner. Do not exceed 2 capsules at day.

Warnings:
• Keep out of reach of children.
• Do not exceed recommended dose.
• If you have a bad reaction to product discontinue use immediately.
• When using nutritional supplements, please inform your physician if you are undergoing treatment for a medical condition or if you are pregnant or lactating.

PENTREXCILINA
Citricillin
500

Eficaz alivio contra las infecciones más comunes

PENTREXCILINA
Citricillin
500

30 capsules

Fast relief of most common infections



Los Cambios Constantes del medio ambiente son causantes de enfermedades por virus, bacterias y hongos, que cada día son más comunes.

Laboratorios Nordimex, desarrollo PENTREXCILINA, fórmula única clínicamente comprobada, con ingredientes potenciales, como: Ajo, equinácea, semilla de toronja y propóleo, que integrados vienen a combatir de manera NATURAL y eficaz los microorganismos que propician las enfermedades infecciosas.

PENTREXCILINA es el medicamento NATURAL para un rápido alivio fortaleciendo el sistema inmunológico, brindando Salud y Energía!

*Academia estadounidense de médicos de la familia.

Modo de Uso:
Niños mayores de 12 años y Adultos: tomar 2 cápsulas cada 8 horas durante 5 días, no exceder de 6 cápsulas al día.
Niños de 6 a 12 años: Tomar 1 cápsula cada 8 horas, no exceder de 3 cápsulas al día.

No se deje al alcance de los niños.
Consérvese en lugar fresco y seco.
No se use durante el embarazo, la lactancia ni en niños menores de 6 años

Dr. Octavio



PENTREXCILINA
Citricilina
500

30 cápsulas

Eficaz alivio contra las infecciones más comunes



Supplement Facts		
Serving Size	1 Capsule	
Servings Per Container	30	
		% DV
PROPRIETARY BLEND	747.5 mg	**
Garlic (<i>Allium sativum</i>)		**
Echinacea (<i>Echinacea purpurea</i>)		**
Golden Seal		**
Propolis powder		**
Astragalus (<i>Astragalus membranaceus</i>)		**
Grapefruit seed extract (<i>Vitis vinifera</i>)		**
Milk Thistle (<i>Silybum marianum</i>)		**
**Daily value not established. % DV Based on a 2,000 Calorie Diet.		
Other Ingredients: Gelatin, magnesium stearate, water. Contains corn and rice. This product contains NO milk, egg, fish, peanuts, crustacean shellfish, tree nuts, wheat, yeast, or gluten. Contains NO artificial sweeteners, flavors, colors or preservatives.		
Dosage and Use: Children 12 years and older: Take 2 capsules every 8 hours with meals, or as recommended by a healthcare practitioner. Children 6 to 12 years old: Take 1 capsule every 8 hours, not to exceed 3 capsules at day. Do not exceed 6 capsules per day.		
Warnings:		
<ul style="list-style-type: none"> • Keep out of reach of children. • Do not exceed recommended dose. • If you have a bad reaction to product discontinue use immediately. • When using nutritional supplements, please inform your physician if you are undergoing treatment for a medical condition or if you are pregnant or lactating. 		

LABORATORIOS NORDIMEX LLC
San Diego, CA. 92154
Dist By:





Supplement Facts

Serving Size 1 Lozenge / tableta

	Amount per Serving	%DV
Vitamin C (Ascorbic Acid)	207mg	345%
Salicin (from White Willow Bark)	200mg	*
Methylsulfonylmethane	300mg	*
Zinc Glycinate	100mg	*

*Percent Daily Value (DV) Not Established

Other Ingredients: Sorbitol, Menthol Crystals, Syzygium aromaticum, Acesulfame, Potassium, Silica, Calcium Stearate, Tangerine Flavor.

DIRECTIONS: Allow 2 lozenges to dissolve slowly in the mouth; may be repeated every 4 hours for a period no longer of 4 days. If slight pains continues, consult your physician. Administration: Oral. Do not use by pregnant women or nursing. Store in a fresh and dry place. Protect from sun light. Keep out of reach of children.

DOSIS: Chupar 2 tabletas cada 4 horas por un periodo no mayor a 4 dias. Si continuan las molestias consulte a su medico. Via de Administración: Oral. No se use en el embarazo y lactancia. Consérvese a temperatura ambiente a no más de 30°C y en lugar seco. Protéjase de la luz. No se deje al alcance de los niños.



**NUEVO
NEW**

angin

**XTRA
FORTE**

**SABOR MANDARINA
TANGERINE FLAVOR**

**30 TABLETS
CONTENIDO NETO 30 TABLETAS**



**TABLETS
TABLETAS**



*Dr.
Octavius*

LABORATORIOS NORDIMEX CO.,
San Francisco, CA. 94538
Dist. by:



10

30 Dolo-Neuro Xtra Forte

Dolo Neuro Xtra Forte

Thiamin
Pyridoxine
Cyanocobalamin
Folic Acid



Bottle with
30 Capsules



a Forte

30 Dolo-Neuro Xtra Forte

Dolo Neuro Xtra Forte

Modo de Uso:

Tomar una capsula al dia.

No se deje al alcance de los niños.

Consérvese en lugar fresco y seco.

No se use durante el embarazo,
la lactancia ni en niños menores
de 12 años.

*Este producto está
recomendado para ayudar en:*

- Relajamiento muscular,
- Problemas de estres,
- Agotamiento físico y mental
- Es un eficaz antiinflamatorio muscular.

*Dr.
Octavio*

30 Dolo-Neuro Xtra Forte

Dolo Neuro Xtra Forte

Tiamina
Piridoxina
Cianocobalamina
Acido Fólico



Frasco con
30 Cápsulas



30 Dolo-Neuro Xtra Forte

Supplement Facts

Serving Size	1 Capsule
Servings Per Container	30
	% DV
Calcium Ascorbate (Equivalent to Vitamin C)	100mg 166.67%
Folic acid	0.5mg 1250.00%
Thiamin Mononitrate (Vitamin B1)	38mg 2400.00%
Riboflavin (Vitamin B2)	5mg 294.12%
Pyridoxine Hydrochloride (Vitamin B6)	10mg 500.00%
Cyanocobalamin (Vitamin B12)	18mg 300.00%
Iron	18mg **
Curcumin blend	175 mg **
Rutin	5 mg **

**Daily value not established. % DV Based on a 2,000 Calorie Diet.

Other Ingredients: Gelatin, magnesium stearate, water. Contains corn and rice. This product contains NO milk, egg, fish, peanuts, crustacean shellfish, tree nuts, wheat, yeast, or gluten. Contains NO artificial sweeteners, flavors, colors or preservatives.

Dosage and Use: Take one capsule per day with meals, or as recommended by a healthcare practitioner.

Warnings:

- Keep out of reach of children.
- Do not exceed recommended dose.
- If you have a bad reaction to product discontinue use immediately.
- When using nutritional supplements, please inform your physician if you are undergoing treatment for a medical condition or if you are pregnant or lactating.



LABORATORIOS NORDIMEX CO.
San Francisco, CA. 94538

Dist By:

Migraña

SedalFort
Bromelina, Curcumina, Boswellia
El alivio natural
contra el Dolor

El alivio natural
contra el Dolor

SedalFort
Bromelina, Curcumina, Boswellia

Migraña

Suplemento Alimenticio
Contenido 30 Gelcaps



SedalFort Migrane es la mejor alternativa natural contra el dolor. Su formulación única ayuda a un alivio rápido sin efectos secundarios. Laboratorios Nordimex, siempre innovando en beneficio de su salud.

Dr. Octavius

Ingredientes

Bromelina, Concentrado de Curcumina, Boswellia (*Boswellia serrata*), Te Verde (*Camellia sinensis*), CMO.

Otros ingredientes

Fosfolípidos de Lecitina, Aceite de Coco, Aceite de Sesame, Gelatina Kosher.

Instrucciones

Tomar 2 gelcaps cada 4 horas y reducir según sea necesario.

Precauciones

No utilizar si el sello de seguridad está roto. Tome sólo como se indica. No está recomendado su uso para menores de 15 años.

Este producto no es recomendado para mujeres embarazadas o en lactancia.

Si está tomando medicamentos o tiene una condición médica, consulte con su médico antes de usar este producto. No exponer el producto a la luz solar.

Para obtener la potencia máxima del producto, consérvese a temperatura ambiente (68-77°F). No se deje al alcance de los niños.

ESTE PRODUCTO NO ES UN MEDICAMENTO.

**The Natural
Pain Reliever**

SedalFort
Bromelain, Curcumin, Boswellia

Migraine

Dietary Supplement
Net Content 30 Softgels



Supplement Facts

Serving Size	1 Gelcaps
Servings Per Container	30
	% DV
PROPRIETARY BLEND	495 mg **
Bromelain	**
Curcumin Concentrate	**
Boswellia (<i>Boswellia serrata</i>)	**
Green Tea (<i>Camellia sinensis</i>)	**
CMO	

**Daily value not established. % DV Based on a 2,000 Calorie Diet.

Other Ingredients: Phospholipids from Lecithin, Coconut Oil, Sesame Oil, Kosher Gelatin.

Suggested Use

Take 2 soft gels every 4 hours for 3 days and then reduced as needed.

Warnings:

- Do not use if inside wrap is broken.
- Take only as directed. Not intended for use by those under 15 years of age.
- This product is not to be taken by pregnant or lactating woman.
- If you are taking medication or have a medical condition, consult a physician before using this product.
- Do not expose product to sunlight.
- To help maintain maximum product potency store at controlled room temperature (68-77°F).
- Keep out the reach of children in a cool and dry place.



Lot / Lote No.

Expiration date
Fecha de Caducidad:

Price:
Precio Máximo
al público:



0 91965 01019 7

ex, LLC FEI: 3008937007
go, CA 92154
2, 25, 31/2011 SJD ZB
16 page 1 of 1

Maravillas y propiedades de la Leche de Alpiste

Es una **excelente fuente de antioxidantes**, los cuales previenen el envejecimiento y desgaste prematuro de la piel.

Poseen una potente capacidad de recarga enzimática.

Las enzimas de esta maravillosa semilla, son un **remedio natural** ideal para desinflamar órganos vitales como el **hígado, los riñones y el páncreas**: el alpiste es un regenerador pancreático poderoso, por lo que ayuda notablemente a erradicar la **diabetes**, además:

- Recarga los **RIÑONES** de enzimas, para ayudar a eliminar los excesos de líquidos.
- Previene **ARTEROESCLEROSIS**.
- Ayuda en casos de **GOTA**.
- **GASTRITIS Y ÚLCERAS** de estómago.
- Ideal para combatir la **HIPERTENSION**.
- Contiene Lipaza, una enzima que **ayuda a depurar grasas nocivas en las venas, arterias** o simplemente de los depósitos de grasa, por lo que sirve como un remedio extraordinario contra la **OBESIDAD, CELULITIS y ABDOMEN ABULTADO**.



Polvo para preparar Bebida Instantánea de

Alpiste

Leche de Canary seed milk

Dietary Supplement
Suplemento Alimenticio



Net Content 454g (1lb)



Canary Seed Milk Instant Beverage Powder

INGREDIENTS: Alpiste (*Phalaris canariensis*), Rice, protein, Psyllium Husk, Oat Bran, Stevia, Cinnamon, Resveratrol.

DIRECTIONS:

Adults & Children 12 years and older:
Add 2 tablespoons of Canary Seed Powder Milk to a cup of water (200 mL approx.) and mix until dissolves, for best results drink 1 cup in the morning and 1 at night.

Children 6 to 12 years old:
Add 1 tablespoon of Canary Seed Powder Milk to a cup of water (200 mL approx.) and mix until dissolves, for best results drink 1 cup in the morning and 1 at night.

Keep in a dry & cool place. Do not consume during pregnancy, diarrhea, abdominal pain & hemorrhoids.

INGREDIENTES: Canary seed (*Phalaris canariensis*), Arroz, proteína, Cáscara de Psyllium, Salvado de Avena, Stevia, Canela, Resveratrol.

MODO DE USO:

Niños mayores de 12 Años y Adultos:
Agregue 2 Cucharadas Soperas (30g) de Leche de Alpiste en Polvo a 1 vaso con agua (200 mL) aprox. Agítense bien hasta homogenizar. Para mejores resultados beber 1 vaso por la mañana y 1 por la noche.

Niños de 6 a 12 Años: Agregue 1 Cucharada Soperas (30g) de Leche de Alpiste en Polvo a 1 vaso con agua (200 mL) aprox. Agítense bien hasta homogenizar. Para mejores resultados beber 1 vaso por la mañana y 1 por la noche.

Consérvese en lugar fresco y seco. Manténgase fuera del alcance de los niños. No consumirse durante el embarazo diarreas, dolor abdominal y hemorroides.



LABORATORIOS NORDIMEX CO.
San Diego, CA. 92154
Ph. (415) 839-9581
Fax (510) 402-4921



Este producto está
recomendado para ayudar en:

- Relajamiento del sistema nervioso
- Problemas de estrés
- Agotamiento físico y mental

Modo de Uso:

Tomar una cápsula al día.

No se deje al alcance de los niños.

Consérvese en lugar fresco y seco.

No se use durante el embarazo,
la lactancia ni en niños menores
de 12 años.

*Dr.
Octavio*



LABORATORIOS NORDIMEX CO.
San Francisco, CA. 94538
Ph. (415) 839-9581
Fax (510) 402-4921

PRINTED IN MEXICO

Super Complejo B ANTIESTRES

Multivitamínico con CoQ10
y Ácido Fólico

Q10 30

Frasco con 30 cápsulas

Supplement Facts

Serving Size	1 Capsule
Servings Per Container	30
	% DV
Calcium Ascorbate (Equivalent to Vitamin C)	100mg 166.67%
Folic acid	0.5mg 1250.00%
Thiamin Mononitrate (Vitamin B1)	36mg 2400.00%
Riboflavin (Vitamin B2)	5mg 294.12%
Pyridoxine Hydrochloride (Vitamin B6)	10mg 500.00%
Cyanocobalamin (Vitamin B12)	18mg 300.00%
Iron	18mg **
Rutin	5 mg **
CoQ10	10mg **

** Daily value not established. % DV Based on a 2,000 Calorie Diet.

Other Ingredients: Gelatin, magnesium stearate, water. Contains corn and rice. This product contains NO milk, egg, fish, peanuts, crustacean shellfish, tree nuts, wheat, yeast, or gluten. Contains NO artificial sweeteners, flavors, colors or preservatives.

Dosage and Use: Take one capsule per day with meals, or as recommended by a healthcare practitioner.

Warnings:

- Keep out of reach of children.
- Do not exceed recommended dose.
- If you have a bad reaction to product discontinue use immediately.
- When using nutritional supplements, please inform your physician if you are undergoing treatment for a medical condition or if you are pregnant or lactating.

Lot / Lote No.
Expiration date / Fecha de Caducidad:

JARABE PLUS BRONCOLIN^{MR}

...el original
de la abejita!

Supplement Facts / Datos de Nutrición

Serving size 1tbsp/Tamaño por porción 1 cucharada (10 ml)

Serving Per Container / Porciones por envase

Amount Per Serving / Cantidad por envase 240 ml

Calories / Contenido Energético
125.4 KJ (30 Kcal)

Calories from Fat / Calorías de grasa 0

% Daily Value / Ingesta Diaria Recomendada*

Total fat / Grasas (lípidos) 0 g 0 %

Wich of / Del cual

Saturated fat / Grasa saturada 0g 0 %

Monounsaturated fat / Grasa monoinsaturada 0 g

Polyunsaturated fat / Grasa poliinsaturada 0 g

Cholesterol / Colesterol 0 mg 0 %

Sodium / Sodio 57 mg 2 %

Total Carbohydrate / Carbohidratos totales 9 g 3 %

Dietary Fiber / Fibra dietética 0 g

Sugars / Azúcares 4 g

Protein / Proteína 0 g

Vitamin A / Vitamina A 0 % Calcium / Calcio 2 %

Vitamin C / Vitamina C 0 % Iron / Hierro 4 %

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be greater or lower depending on your calorie needs. * Porcentaje de valor diario recomendado está basado en 2,000 calorías de dieta. Su valor diario depende sobre su necesidad de calorías.

INGREDIENTES:

**Honey, Extract propolis, Eucalyptus, Gordolobo, Saucó, Echinacea, Fenugreek, Purple onion, Garlic, Mirra, Bugambilia, Menthol, Lemon Essence, Essence of Honey.

**Valores no establecidos / Values not established

SUGERENCIA DE USO

Adultos: Tomar un vasito cada dos horas.

Niños: Tomar medio vasito cada 2 horas.

Para obtener un rápido alivio de las vías respiratorias causadas por la tos y el resfriado tome 2 ó 3 vasitos de Jarabe BRONCOLIN PLUS^{MR} en té caliente, de preferencia en té de Eucalipto, Gordolobo, Canela, Manzanilla, Yerbabuena, Menta o el té que a usted más le agrade.

Elaborado por:
DISTRIBUIDORA DE ALIMENTOS
NATURALES Y NUTRICIONALES, S.A. DE C.V.
Manuel Avila Camacho No. 44-A
Col. Ejidos de Sta. Ma. Aztahuacan 09570
México, D.F.

Tel. 5642-1280 Fax 5690-7517

HECHO EN MEXICO



Nordimex, LLC FEI: 3008937007
San Diego, CA 92154
EI: 5/12, 25, 31/2011 SJD ZB
Exhibit 4 page 1 of 1

...el original
de la abejita!

BRONCOLIN^{MR} PLUS

JARABE

AUXILIAR EN LAS
MOLESTIAS DE LAS
VÍAS RESPIRATORIAS
CAUSADAS POR LA TOS
Y EL RESFRIADO

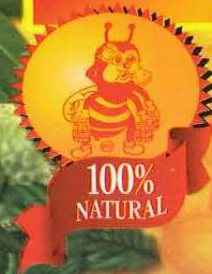


...el original
de la abejita!

BRONCOLIN^{MR} PLUS

JARABE

CON
EXTRACTOS
HERBALES,
PROPOLIS
Y MIEL DE
ABEJA



Contenido Neto: 240 ml. (31.1 fl. oz.)

SUPLEMENTO ALIMENTICIO DIETARY SUPPLEMENT

ESTE PRODUCTO NO ES UN MEDICAMENTO.
THIS PRODUCT IS NOT A MEDICINE.

Instrucciones para su consumo:

Adultos y niños mayores de 12 años tomar

2 cucharadas cada 4 horas.

Niños menores de 12 años tomar

1 cucharada cada 4 horas.

Instructions for consumption:

Adults and children over 12 years take

2 tablespoons every 4 hours.

Children under 12 years take

1 tablespoon every 4 hours.

Ingredientes:

Miel de abeja, Extracto de propóleo, Eucalipto, Gordolobo, Saucó, Equinácea, Fenogreco, Cebolla morada, Ajo, Mirra, Bugambilia, Mentol, Esencia de Limón, Esencia de Miel.

Ingredients: Honey, extract propolis, Eucalyptus, Gordolobo, Saucó, Echinacea, Fenugreek, Purple onion, Garlic, Mirra, Bugambilia, Menthol, Lemon Essence, Essence of Honey.

Instrucciones para su conservación:

Consérvese en un lugar fresco y seco, a una temperatura no mayor a 30° C.

No se deje al alcance de los niños.

El consumo de este producto es responsabilidad de quien lo recomienda y de quien lo usa.

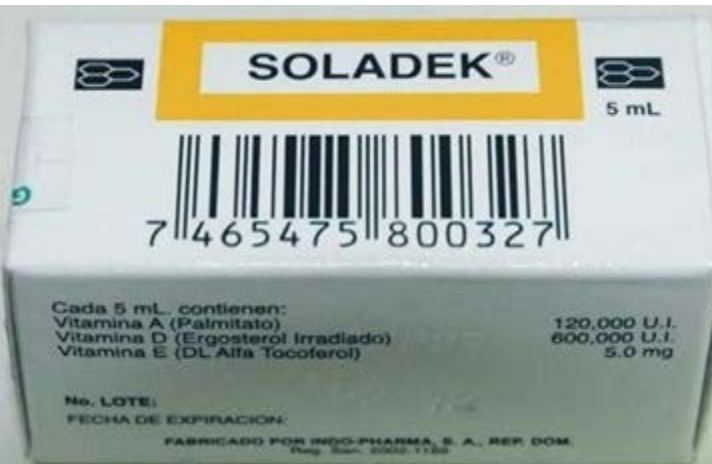
Instructions for conservation:

Keep in a cool, dry place for a

temperatures no higher than 30° C.

Do not let the reach of children.

The consumption of this product is the responsibility who recommended and who uses it.




GRIPA Y ALERGIAS

XXL-6

Rápido Alivio

**Antigripal
efervescente**



**POLVO EFERVESCENTE
SABOR LIMON
120g / 4 oz.**

Supplement Facts

Servings size	1 Heaping Tablespoon (5g/0.17 oz)	
Servings per Container	Approx. 30	
	Amount per serving	% DV
Vitamin A (as Retinol Palmitate)	100,000IU	2,000%
Vitamin C (as Ascorbic Acid)	1,000IU	1,667%
Bicarbonates (from Sodium & Potassium Bicarbonate)	1,000mg	*
Stevia Leaf Extract	55mg	*
Echinacea Purpurea Whole Herb Extract	20mg	*

*Percent Daily Values (DV) Not Established.

Other Ingredients:
Maltodextrin, Natural flavors.
No: Wheat, Soy, Peanut, Tree Nut, Fish, Shellfish, Egg or Milk.

This product contains levels of vitamin A greater than 10,000 IU/day which may cause congenital deformity, fatigue, headache and should never be used during pregnancy.
These statements have not been evaluated by The Food and Drug Administration.
This product is not intended to diagnose, treat, cure or prevent any diseases.

SUGGEST USE
Take 1 heaping tablespoon (5g) 2 times a day in 4 oz of water for three days to support the restoration of your mucous membranes.
For those below 12 years of age, use 1 rounded teaspoon (2g) 2 times a day for three days.

MODO DE USO SUGERIDO
Mezcle una cucharada (5g) en un vaso con agua (4 oz), 2 veces al día durante 3 días para ayudar a la restauración de las membranas mucosas.

Niños menores de 12 años: Mezclar una chucharadita (2g), 2 veces al día durante 3 días.



XtraForte

DESIN-FLANAX 850

Nuevo

DESIN-FLANAX 850

XtraForte



**PAIN RELIEF &
ANTI-INFLAMMATORY CAPS
ARTHRITIS & RHEUMATISM**

30 CAPSULES

DESIN-FLANAX 850

XtraForte

Sugerencia de Uso:
Tomar 2 cápsulas cada 8 horas según lo requiera.
No exceder de 8 cápsulas en 24 horas.

No se deje al alcance de los niños.
Consérvese en lugar fresco y seco.
No exceda la dosis recomendada.
Si presenta alguna reacción al producto,
discontinúe su uso inmediatamente.
Consulte a su médico para su uso
durante el embarazo y la lactancia.

*Este producto está
recomendado para ayudar como:
Anti-inflamatorio y Analgésico
contra dolor de espalda, cabeza,
huesos, Artritis y Reumas.*

Dr. Octavio

Nuevo

DESIN-FLANAX 850

XtraForte



**ANTI-INFLAMATORIO
Y ANALGESICO
ARTHRITIS Y REUMAS**

CONTENIDO NETO 30 CAPSULAS

Supplement Facts	
Serving Size	2 Capsules
Servings Per Container	30
Amount per serving	
Calories	<1
Calories From Fat	0
Sugar	0
Sodium	10 mg
Dietary Fiber	50 mg
Total Protein	<1 gm
Total Carbohydrates	<1 gm
All Above values are less than 2% Daily Value	
Serving size: 1 capsule	
Curcumin (From Turmeric Root Ext)	250mg*
D.L. Phenylalanine	75mg*
Boswellia Serrata Herb Extract	175mg*
Nattokinase	2.5mg*
*Percent Daily Value Not Established.	
Other Ingredients: Magnesium Stearate, Vegetable, Gelatin Capsule.	
Suggested Use: 2 capsules every 8 hours, or as needed. Not to exceed 8 capsules in 24 Hours.	
Recommended Use: Back pain, headache, arthritis.	
Warnings: • Keep out of reach of children. • Do not exceed recommended dose. • If you have a bad reaction to product discontinue use immediately. • When using nutritional supplements, please inform your physician if you are undergoing treatment for a medical condition or if you are pregnant or lactating.	



LABORATORIOS NORDIMEX CO.
San Francisco, CA. 94538
Dist By:

DESIN-FLANAX 850

XtraForte



Supplement Facts

Serving Size 1 bottle 6.8 fl. Oz (200 ml)

	Amount per Serving	% Daily Value
Calories	110	
Total Carbohydrate	26 g	9 % [†]
Sugars	26 g	††
Niacin	8 mg	100 %
Vitamin B6	5 mg	250 %
Vitamin B12	4 mg	83 %
Pantothenic acid	4 mg	50 %
Sodium	75 mg	3 %

Proprietary blend 975 mg

Damiana leaf powder extract^{††}, schizandra berry powder extract^{††}, muirapuama root powder extract^{††}, guarana seed powder extract^{††}, oriental ginseng root powder extract^{††}, taurine (as l-aurine hydrochloride)^{††}

[†]Percent Daily Values are based on a 2000 calorie diet
^{††}Daily Value not established.

Other ingredients: Carbonated water, sugar, citric acid, tri-sodium citrate, artificial flavors, sodium benzoate and potassium sorbate (preservatives); caffeine, color FD&C Blue No.1

[†]These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

This product contains a proprietary herbal blend with powder extract of Damiana, Schizandra, Muirapuama, Guarana, Oriental Ginseng, and Taurine.

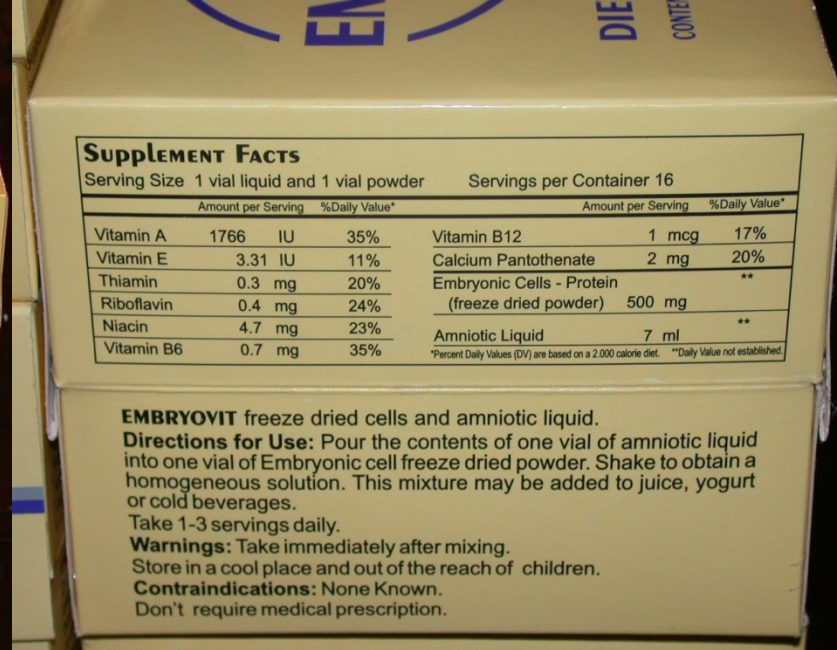
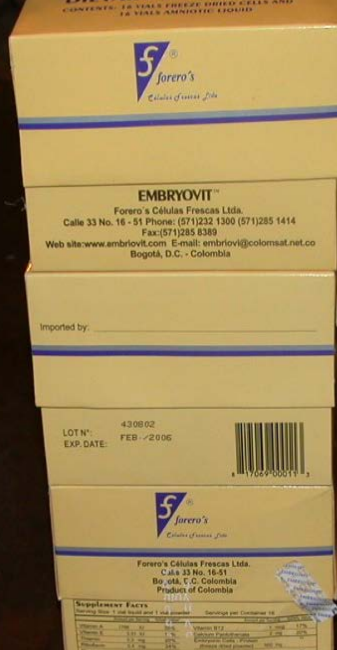
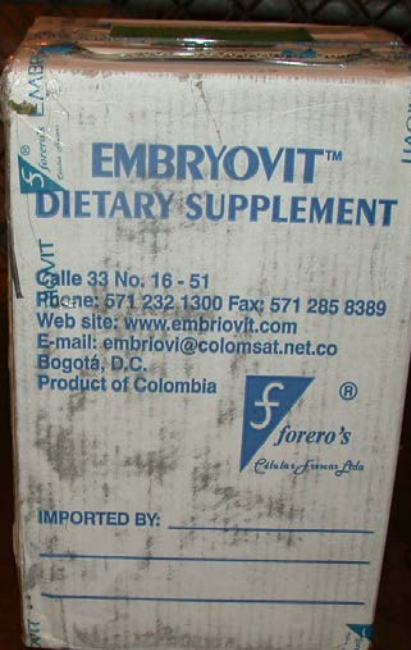
Not suitable for pregnant women sensitive to caffeine

Produced exclusively in THE LOVE FACTORY, 16950 Dallas Parkway, Dallas, Texas 75248

Made in Germany

www.thelovefactory.com
1-866-568-2222







EMBRIOVIT® Dietary supplement can be consumed by the whole family; it has no age or health condition limitations..

who wishes to remain healthy, or for any individual who for different reasons may have health problems or is prone to have them. EMBRIOVIT® Dietary supplement can be used for:

- Skin problems due to tissue degeneration or hardening, due to different causes such as burns, wounds, etc.
- Sexual hormone metabolism deficiency, which may cause inhibition in procreation capacity.
- In patients with blood related problems, such as anaemia and certain types of leukaemia, improving the resistance and protection of red blood cells.
- For individuals with endocrine problems, helps to stimulate the production of hormones.
- Prevents cardiovascular deterioration
- For people who have neurological problems, Vitamin B₁ and B₆ are beneficial.
- Can contribute to skin, nails and hair protection, in different pathological processes.
- Stimulates body physical capacity, reducing fatigue.
- Avoids the early reduction of visual acuity.
- Stimulates the protection of tissue for different illnesses, due to the fact that it co-operates with the synthesis of amino acids and nucleic acids.
- Prevents problems to the central nervous system with its Vitamin B₁₂.
- Contributes to the prevention of stomach and intestinal tract illnesses.

HOW DO THE BENEFITS SHOW ?

They begin to appear progressively as the organism assimilates the nutrients supplied. The speed in which the change is noticed depends on the individual's particular metabolism.

DIVINE NONI®

- Diabetes
- Paralysis
- Obesity
- Cancer
- Blood Pressure
- Headache; Toothache
- Arthritis
- Alopecia
- Indigestion
- Heart Disease
- Abdominal Pain
- Abdominal Pain from Occasional Indigestion
- Constipation
- Stomach ache, Ulcer
- Cold, Tuberculosis
- Skin Diseases
- Stress
- Menstrual Problems
- Kidney Diseases
- Allergy, Asthma
- Nervous Weakness
- Lack of Immune Power
- Maintains testosterone to normal levels

Bonus Question

Directions: Drink as directed. Noni is a cool refreshing beverage that you can enjoy.

Think what????





Thanks

- DDSP: Cara Welch, Acting Division Director
- ORA: Jason Humbert and Gary Coody



Questions about Regulations, Enforcement, Advice on Dietary Supplements:

Contact the Division of Dietary Supplement Programs:

Cara Welch HFS-810 CPK1 (4D-024)
Cara.Welch@[fda.hhs.gov](mailto:Cara.Welch@fda.hhs.gov) (240) 402-1850

[Constance J. Hardy@fda.hhs.gov](mailto:Constance.J.Hardy@fda.hhs.gov) (240) 402-2333
Constance Hardy HFS-810 CPK1 (4D-007)

5100 Paint Branch Parkway HFS-810 CPK1
College Park, MD 20740



Appendix

Clarify Legal Terms

- Act: A bill passed by both houses of Congress that has become law.
- Statute: A law enacted by a legislature.
(once an Act is published in *Statutes at Large*, they are the same as a statute.)
- <http://govpubs.lib.umn.edu/guides/leg.phtml?faq=1>

Clarify Legal Terms

- Law: The body of rules and principles governing the affairs of a community. Laws will appear in the U.S. Code.
- U.S. Code: The U.S. Code is a compilation of all current law arranged by legal subject.
- <http://govpubs.lib.umn.edu/guides/leg.phtml?faq=1>

Clarify Legal Terms

- The *Statutes at Large* will reprint the Federal Food, Drug, and Cosmetic Act (the Act) exactly as it passed Congress, e.g., section **413** of the Act
- In the U.S. Code will be found the elements of the Act under the appropriate title/subject, e.g., 21 U.S.C. **350b** New Dietary Ingredients or 21 U.S.C. § 350b

Clarify Legal Terms

- Code of Federal Regulations: A regulation is developed after an enabling statute is created. Think of U.S.C. as the enabling law – what you are supposed to do – and the CFR as the regulation – how you are supposed to do it.